

II. REMARKS

A. Status of the Claims

Claims 1, 2 and 4-17 are currently pending. Claims 1, 2 and 8 have been amended without prejudice. It is respectfully submitted that no new matter has been added by virtue of this amendment.

B. Rejection of Claims 1-2, 4-8 and 11-17 under 35 U.S.C. § 102(b)

In the Office Action, the Examiner rejected claims 1-2, 4-8 and 11-17 under 35 U.S.C. § 102(b) as anticipated by Stinchcomb et al.

In response, claim 1 has been amended without prejudice to recite a compound of Formula I, wherein the straight or branched chain alkyl portion of the alkylcarbonyl moiety of R₁ has from 8 to 20 carbon atoms. It is respectfully submitted that Stinchcomb et al. fails to teach or suggest this limitation.

Further, it is respectfully submitted that Stinchcomb et al. fails to teach or suggest a compound of Formula I, wherein the composition is in a form selected from the group consisting of an oral, sublingual, implantable, intranasal, inhalable and parenteral dosage form, as recited in present claim 17.

In view of the actions taken and arguments presented, Applicants respectfully submit that the rejection of claims 1-2, 4-8 and 11-17 under 35 U.S.C. § 102(b) over Stinchcomb et al. be withdrawn.

C. Rejection of Claims 9 and 10 under 35 U.S.C. §112

In the Office Action, the Examiner rejected claims 9 and 10 under 35 U.S.C. § 112. The Examiner referred to page 7 of the specification and stated that the disclosure "fails to provide adequate teachings to make compounds of claims 9 and 10 since the term 'modifying' does not provide any reagent(s) and reaction condition(s) to make the claimed compounds."

The rejection is respectfully traversed. "An applicant's specification must enable a person skilled in the art to make and use the claimed invention without **undue** experimentation." (Emphasis added) MPEP 8th Ed. 2nd Rev. § 2106 (V)(B)(2).

Further, "" ... a patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art. *Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys.*, 804 F.2d 659, 664 (Fed. Cir. 1986); *In re Howarth*, 654 F.2d 103, 105 (CCPA 1981) ("An inventor need not, however, explain every detail since he is speaking to those skilled in the art."); *In re Lange*, 644 F.2d 856, 863 (CCPA 1981). We thus have noted that "not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be." *In re Gay*, 50 C.C.P.A. 725, 309 F.2d 769, 774, 1962 Dec. Comm'r Pat. 737 (CCPA 1962). Unless there is evidence to the contrary, therefore, the lack of certain production details does not indicate failure of enablement. See *DeGeorge v. Bernier*, 768 F.2d 1318, 1323 (Fed. Cir. 1985)."" *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir., 2004).

Applicants respectfully submit that the presentation of the structure of Formula II in the present application is sufficient to enable one of ordinary skill in the art to make the compounds utilizing art recognized procedures with routine experimentation. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112 be removed.

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III. CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that all pending claims are now in condition for allowance. The Examiner is invited to contact the undersigned by telephone if a telephone interview would advance prosecution of the present application. An early and favorable action is earnestly solicited.

Respectfully submitted,
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